

IN THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. – 13. (Cancelled)

14. (Previously Presented) A medical device, comprising:

- a) a first compliant collagenous biomaterial;
- b) the first compliant collagenous biomaterial having an aperture extending therethrough;
- c) the first compliant collagenous biomaterial also having an extension;
- d) wherein the extension is shaped to be inserted into the aperture, has a width greater than a maximum width of said aperture, and is foldable for receipt through said aperture;
- e) a second biocompatible material disposed on the first biomaterial; and
- f) wherein an intermediate layer is disposed under the second biocompatible material.

15. (Original) The medical device of claim 14, wherein at least one of the second biocompatible material and intermediate layer comprises at least one of a submucosal tissue, mucosal tissue, collagen, partially collagenous biomaterial, and intermediate layer comprises at least one of a submucosal tissue, mucosal tissue, collagen, partially collagenous biomaterial, polytetrafluoroethylene, polyester, stainless steel, DACRON, ORLON, FORTISAN, nylon, polypropylene, polyglactin 910, polyglycolic acid, pericardium, dura tissue, facia lata, a biocompatible material, polymers, co-polymers, a synthetic material, and any combination or part thereof.

16. – 17. (Cancelled)

18. (Currently Amended) A medical device, comprising:

- a) a compliant, sealed tube configured as a leak-resistant vessel graft, the tube having a lumen extending therethrough, the tube formed with a sheet of biomaterial, said sheet of biomaterial having a first side forming a luminal surface of the tube and a second side opposite the first side and forming an external surface of the tube;
- b) wherein the sheet of biomaterial defines tube includes a first extension a plurality of extensions and a plurality of apertures, with each one of said apertures providing an opening extending through said sheet of biomaterial; and adjacent to a first aperture;
- c) wherein each one of said plurality of extensions includes said first extension has a first extension portion received through a corresponding one of said plurality of apertures said first aperture so as to provide a first portion of said sheet of biomaterial overlying a second portion of said sheet of biomaterial ~~overlie an underlying layer of material~~, wherein a said first portion of said sheet of biomaterial surface of said first extension portion conforms and is bonded to the second portion of said sheet of biomaterial ~~underlying layer of material~~ by one or more of dehydrothermal bonding, crosslinking, or bonding with a resorbable or non-resorbable biocompatible bonding agent,;
- ~~d) wherein the tube comprises a collagenous extracellular matrix; and~~
- ~~e) wherein the tube includes a plurality of extensions.~~

19. (Currently Amended) The medical device of claim 18, wherein the biomaterial comprises a collagenous extracellular matrix sheet material~~tube includes a plurality of apertures.~~

20. (Currently Amended) A medical device, comprising:

- a) a compliant, sealed tube configured as a leak-resistant vessel graft, the tube having a lumen extending therethrough, the tube formed with a sheet of collagenous biomaterial

having a first side forming a surface of said lumen and a second side forming an external surface of said tube;

e)b) wherein the sheet of collagenous biomaterial defines a plurality of extensions and a plurality of apertures, with each of the plurality of apertures providing an opening extending through the sheet of collagenous biomaterial; and tube includes a first extension adjacent to a first aperture;

c) ~~wherein said first extension~~ each one of said plurality of extensions has a first extension portion received through ~~said first aperture~~ a corresponding one of said plurality of apertures so as to overlie an underlying layer of material, wherein a surface of said first extension portion conforms and is bonded to the underlying layer of material by one or more of dehydrothermal bonding, crosslinking, or bonding with a resorbable or non-resorbable biocompatible bonding agent;~~;~~ and

d)~~wherein the tube includes a plurality of extensions and apertures, the extensions being inserted into the apertures.~~

21. (Previously Presented) The medical device of claim 20, wherein at least one of the plurality of extensions is larger than at least one of the plurality of apertures.

22. (Previously Presented) The medical device of claim 20, wherein a second biocompatible material is disposed on the tube.

23. (Currently Amended) A medical device, comprising:

a) a compliant, sealed tube configured as a leak-resistant vessel graft, the tube having a lumen extending therethrough, the tube formed with a sheet of biomaterial having a first side forming a surface of said lumen and a second side forming an external surface of said tube;

b) wherein the sheet of biomaterial defines a plurality of extensions and a plurality of apertures, with each of the plurality of apertures providing an opening extending through

the sheet of biomaterial; and ~~the tube includes a first extension adjacent to a first aperture;~~

c) ~~wherein said first extension~~ each one of said plurality of extensions has a first extension portion received through ~~said first aperture~~ a corresponding one of said plurality of apertures so as to overlie an underlying layer of material, wherein a surface of said first extension portion conforms and is bonded to the underlying layer of material by one or more of dehydrothermal bonding, crosslinking, or bonding with a resorbable or non-resorbable biocompatible bonding agent;

~~d) wherein the tube includes a plurality of extensions and apertures, the extensions being inserted into the apertures;~~

~~e)d)~~ wherein a second biocompatible material is disposed on the tube; and

~~f)e)~~ wherein an intermediate layer is disposed under the second biocompatible layer material.

24. (Original) The medical device of claim 23, wherein the intermediate layer comprises at least one of a submucosal tissue, mucosal tissue, collagen, partially collagenous biomaterial, polytetrafluoroethylene, polyester, stainless steel, DACRON, ORLON, FORTISAN, nylon, polypropylene, polyglactin 910, polyglycolic acid, pericardium, dura tissue, facia lata, a biocompatible material, a synthetic material, polymers, co-polymers, and any combination or part thereof.

25. (Currently Amended) The medical device of claim 23, wherein ~~the extension~~ each one of said plurality of extensions also includes a retainer.

26. (Previously Presented) A method of creating a tube, comprising the steps of:

a) forming at least one extension and at least one aperture on a sheet of collagenous biocompatible material;

- b) inserting the at least one extension into the at least one aperture so as to form a tube;
- c) engaging the at least one extension with the at least one aperture, wherein said engaging includes positioning a portion of the at least one extension through the at least one aperture so as to position said portion overlapping an underlying layer of the sheet of collagenous biocompatible material, wherein a surface of said portion conforms to the underlying layer of the sheet of collagenous biomaterial; and
- d) bonding the surface of said portion to the underlying layer of the sheet of collagenous biocompatible material, wherein said bonding comprises one or more of dehydrothermal bonding, crosslinking, or bonding with a resorbable or non-resorbable biocompatible bonding agent.

27. (Previously Presented) The method of creating a tube of claim 26, wherein the steps further includes the step of disposing an intermediate layer on the tube.

28. (Original) The method of creating a tube of claim 27, wherein the steps further includes the step of disposing an outer layer on the intermediate layer.

29. (Previously Presented) The method of creating a tube of claim 26, wherein said bonding comprises crosslinking.

30. (Currently Amended) A medical device, comprising:

- a) a sealed collagenous tube configured as a leak-resistant vessel graft, the tube having a lumen extending therethrough, the lumen having an inner wall, and the tube formed with

a sheet of collagenous material having a first side forming a surface of the inner wall and a second side forming an external surface of the tube;

- b) the ~~tube and~~ sheet having defining a plurality of extensions and a plurality of apertures extending through the sheet, therethrough, the extensions and apertures engaging each other adjacent the inner wall; and
- c) wherein ~~at least one each one~~ of said plurality of extensions includes an extension portion received through a corresponding one of said plurality of apertures so as to overlie an underlying layer of material, wherein a surface of said extension portion conforms and is bonded to the underlying layer of material by one or more of dehydrothermal bonding, crosslinking, or bonding with a resorbable or non-resorbable biocompatible bonding agent.

31. – 35. (Cancelled)

36. (Currently Amended) A medical device, comprising:

a compliant, sealed tube formed from a sheet of collagenous biomaterial, ~~comprising submucosal tissue~~, the tube having a lumen having a lumen wall and configured as a leak-resistant vessel graft; said lumen wall free from any continuous seam edge traversing the entire length of the tube, and said lumen wall including at least one multi-layer region formed by an extension having a surface that conforms and is bonded to the underlying layer of said sheet of biomaterial by one or more of dehydrothermal bonding, crosslinking, or bonding with a resorbable or non-resorbable biocompatible bonding agent;

wherein the lumen wall presents a plurality of longitudinal seam edges;

wherein said seams are formed by intersections of edge portions of said sheet of biomaterial and non-edge portions of said sheet of biomaterial; and

wherein said edge portions are formed at a perimeter of said sheet of biomaterial.

37. (Original) The medical device of claim 36, wherein said tube comprises a plurality of interleaving extensions of said biomaterial.

38. (Previously Presented) A medical device, comprising:

a compliant, sealed tube formed from a sheet of biomaterial comprising submucosal tissue, the tube having a lumen having a lumen wall and configured as a leak-resistant vessel graft; said lumen wall free from any continuous seam edge traversing the entire length of the tube, and said lumen wall including at least one multi-layer region formed by an extension having a surface that conforms and is bonded to the underlying layer of said sheet of biomaterial by one or more of dehydrothermal bonding, crosslinking, or bonding with a resorbable or non-resorbable biocompatible bonding agent; and

wherein said tube comprises a seam formed by a butt joint.

39. -- 45. (Cancelled)

46. (Previously Presented) The medical device of claim 14, wherein said biomaterial comprises a collagenous extracellular matrix material.

47. (Previously Presented) The medical device of claim 46, wherein the collagenous extracellular matrix comprises submucosal tissue.

48. (Previously Presented) The medical device of claim 46, wherein the collagenous extracellular matrix material is porcine.
49. (Previously Presented) The medical device of claim 18, wherein the collagenous extracellular matrix comprises submucosal tissue.
50. (Previously Presented) The medical device of claim 49, wherein the submucosal tissue is porcine.
51. (Previously Presented) The medical device of claim 20, wherein said tube comprises a collagenous extracellular matrix material.
52. (Previously Presented) The medical device of claim 51, wherein the collagenous extracellular matrix material comprises submucosal tissue.
53. (Previously Presented) The medical device of claim 52 ~~[[54]]~~, wherein the submucosal tissue is porcine.
54. (Previously Presented) The method of claim 26, wherein said sheet of collagenous biocompatible material comprises a collagenous extracellular matrix material.
55. (Previously Presented) The method of claim 54, wherein the collagenous extracellular matrix material comprises submucosal tissue.
56. (Previously Presented) The method of claim 55, wherein the submucosal tissue is porcine.
57. (Previously Presented) The medical device of claim 30, wherein said tube comprises a collagenous extracellular matrix material.

58. (Previously Presented) The medical device of claim 57, wherein the collagenous extracellular matrix material comprises submucosal tissue.

59. (Previously Presented) The medical device of claim 58, wherein the submucosal tissue is porcine.

60. (Previously Presented) The medical device of claim 36, wherein the submucosal tissue is porcine.

61. (Previously Presented) The medical device of claim 38, wherein the submucosal tissue is porcine.